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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,851	08/30/2001	David Botstein	P2548P1C7	2329
7590 03/01/2004				
BRINKS HOFER GILSON & LIONE NBC TOWER-SUITE 3600 455 N CITY FRONT PLAZA DRIVE CHICAGO, IL 60611-5599		EXAMINER O HARA, EILEEN B		
		ART UNIT PAPER NUMBER 1646		

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/943,851

Applicant(s)

BOTSTEIN ET AL.

Examiner

Eileen O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-26 and 28-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 22-26 and 28-30 are pending in the instant application. Claims 22 and 25 have been amended, claim 27 has been canceled and claims 28-30 have been added as requested by Applicant in the Paper filed Dec. 15, 2003.

Newly submitted claims 28-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the antibodies of claims 22-26 and the methods of claims 28-30 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in a method of identifying or purifying the polypeptide, but the antibody can be used in another and materially different process from the use for identification or purification, such as in a method of treatment.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Oath/Declaration

2. The objection to the oath is withdrawn due to the removal of the inventor from the application pursuant to a 37 CFR § 1.48(b) letter filed Dec. 15, 2003.

Objection to Specification

3. The objections to the specification are withdrawn in view of Applicants' amendment.

Withdrawn Objections and Rejections

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Double Patenting

5. Applicant's statement on page 7 of the response that to the best of its knowledge, no claims of the present application conflict with claims presented in applications containing SEQ ID NO: 362, is acknowledged and accepted as a complete reply to the requirement under 37 CFR 1.105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 22-26 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record in the previous Office Action at Page 6, and below.

Applicants traverse the rejection and assert that the phrase “specifically binds” is a term of art that has a well-understood meaning in the art, and that “specifically binds” is used throughout the specification in context, including on page 16, lines 1-3 and page 88, lines 13-15.

Applicants’ arguments have been fully considered but are not deemed persuasive. The specification does not define the term “specifically binds” and the term “specifically binds” can have different meanings. It is not clear if Applicants intend the art accepted definition, that is the antibody binds above background, or alternatively, that the antibody binds exclusively to the protein of SEQ ID NO: 42. If Applicants intend the latter, a rejection under 35 U.S.C. 112, first paragraph for enablement would be made over the claims. Therefore, the rejection is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 22-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have amended the claims to recite a functional limitation not found in the Sheppard patent, namely, the claimed antibody binds an epitope of the polypeptide of SEQ ID NO: 42, which binding prevents inhibition of neoplastic growth in tumor cells by the polypeptide of SEQ ID NO: 42, and state that this amendment is supported in the specification at page 31,

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lines 9-15, page 33, lines 11-20 and page 138, beginning at line 13. However, these sections of the specification only teach that antibodies can be generated by the PRO344 polypeptide, that define “isolated” antibody, and that antibodies against the PRO344 polypeptide are useful for affinity purification of the polypeptide. There is no specific teaching of an antibody that would prevent inhibition of neoplastic growth in tumor cells, and therefore this is new matter.

Claim Rejections - 35 USC § 102

8. The rejection under 35 USC § 102 has been withdrawn in view of Applicant’s amendment to the claims, drawn to a functional limitation not found in the Sheppard patent, namely, the claimed antibody binds an epitope of the polypeptide of SEQ ID NO: 42, which binding prevents inhibition of neoplastic growth in tumor cells. However, this limitation is new matter, as discussed above. If Applicants remove the limitation, the rejection would be reinstated.

It is believed that all pertinent arguments have been answered.

Conclusion

9. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

Official papers Before Final and After Final filed by RightFax should be directed to (703) 872-9306.

The customer service RightFax number is (703) 872-9305.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Eileen B. O'Hara, Ph.D.

Patent Examiner



LORRAINE SPECTOR
PRIMARY EXAMINER